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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,118

07/31/2003

Matthew B. Wheeler

99-02

1839

23713

7590

05/10/2006

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,118

Applicant(s)

WHEELER ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/31/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application filed July 31, 2003, claims benefit of 60/400,287, filed 07/31/2002.

Claims 1-21 are pending.

Election/Restrictions

Applicants election filed February 22, 2006 has been received and entered. It was noted that this application contains claims directed to patentably distinct species. Upon review of the specification Examiner does not consider it an undue burden to examine all the species set forth in the claims.

Accordingly, the election of species in the restriction requirement is withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 14, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. It is noted that the specification provides for numerous citations of reference, many of which appear to be listed in Applicants' IDS. However, the Examiner has not provided a one to one comparison of the references listed in the specification. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted

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in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing non-primate mammal by methods of nuclear transfer, does not reasonably provide enablement for any non-human animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or

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absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The primary issue focuses on the ability to practice methods of nuclear transfer successfully in any non-human mammal, in particular in other primates. These embodiments are not enabling because of the art-recognized inability to clone primates by methods of nuclear transfer. Vogel [*Science*, 300:226-227 (2003)] state that Rhesus monkey nuclear transfer-generated embryos seemed normal at their early stages but were unable to develop further when implanted into a surrogate mother. This was because the cells had the wrong number of chromosomes, and that this aneuploidy resulted in the abortion of the fetus. This was found to also be the case with human nuclear transfer embryos. See p. 225. Simerly *et al.* [*Science*, 300:297 (2003)] state that, "Primate nuclear transfer appears to be challenged by stricter molecular requirements than in other animals ... With current approaches, nuclear transfer to produce embryonic stem cells in nonhuman primates may prove difficult - and reproductive cloning unachievable." See p. 297, 3rd column, last sentence. As the state of the art evidences that nuclear transfer in primates is unpredictable, and the instant specification fails to provide teachings to show that primate nuclear transfer using the claimed methods would result in pluripotent mammalian cells, it would have required undue experimentation for one of skill in the art to make and use the claimed invention.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 14, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato *et al.* (Human Cell, 13(4):197-202, Dec 2000).

The claims broadly encompass the production of any non-human mammal by using ES cells in nuclear transfer methodology. Kato *et al.* disclose that mouse ES cells were known at the time of filing and provide evidence that methods of nuclear transfer can be used to generate a viable fetus. Kato *et al.* disclose that ES cells can be manipulated to comprise a transgene, and with the proof of principle that they can successfully serve as a donor to produce a fetus, can serve be used in conjunction with methods conventional in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmut *et al.* (1997), Campbell *et al.* (1997) and Wheeler *et al.* (1996)(IDS references).

At the time of filing Wilmut *et al.* and Campbell *et al.* teach methods of nuclear transfer, in particular that totipotent cells can be used successfully to generate viable embryos that can be subsequently implanted into pseudo-pregnant females to carry to term (see also page 21 of the specification). While each provide the basis of using any species of mammal, neither specifically teach to practice the method with the species of porcine, in particular that porcine ES cells existed. At the time of filing Wheeler *et al.* teach that porcine totipotent ES cells existed, and could be isolated from porcine animals. In particular, Wheeler *et al.* teach that similar to mouse ES cells the porcine ES cells could be used in the generation of transgenic swine.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the porcine ES cells taught by Wheeler *et al.* in the nuclear transfer methods generally disclosed by Wilmut *et al.* and Campbell *et al.* One having ordinary skill in the art would have been motivated to substitute the use of ES cells because they allow for continued proliferation, and the ability to practice homologous recombination to affect

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an endogenous gene. The methods of manipulating ES cells is routine, and given the disclosure and success of Wilmut *et al.* and Campbell *et al.* there would have been a reasonable expectation of success to practice methods of nuclear transfer with porcine ES cells.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

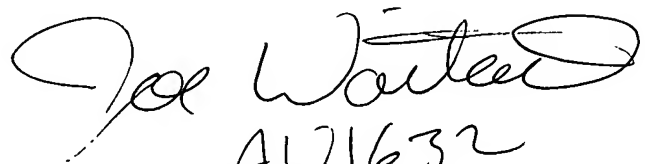
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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